REMARKS

Reconsideration of this application, as amended, is respectfully requested.

At the outset, it is gratefully acknowledged that the Examiner has kindly withdrawn the objection to Claims 1-9 and 15-22; the rejection of Claims 1-9, 13, 14 and 18 under 35 U.S.C. § 112, second paragraph; the rejection of Claims 10-14 under 35 U.S.C. § 112, first paragraph; and the rejection of Claims 19-21 under 35 U.S.C. § 112, first paragraph.

Also, the undersigned attorney wishes to sincerely thank the Examiner for taking the time to discuss this case recently on the telephone with her. The discussion was extremely useful to identifying the focus of the present response. As the Examiner will soon appreciate, the instant specification does exclude the addition of the essential ingredient of the cited art, namely, interferon, from the scope of the claimed invention.

Generally speaking, the Examiner relies on Poston *et al.*, feeling that there is no difference between the results of Applicant and the teachings of Poston *et al.* In particular, the Examiner sees no surprising result. Applicant, on the hand, argues that Poston *et al.* require the critical addition of interferon to all forms or administration of their *in ovo* vaccine and do not teach or imply that this crucial ingredient can be omitted from the *in ovo* vaccine without significant, adverse effect. It is shown that Poston *et al.* describe that every embodiment of the invention in the Abstract, the Detailed Description of the Invention, the Examples and the claims must include interferon in conjunction with the live, pathogenic viruses. Poston *et al.* neither teach nor imply that interferon is optional or can be omitted from the *in ovo* method of administration without negative consequences.

The guidelines of M.P.E.P. § 2144.04, citing the case of *In re Edge*, 359 F.2d 896, 149 U.S.P.Q. 556 (C.C.P.A. 1966), indicate that the omission of an element with retention of the element's function is an indicia of unobviousness. Therefore, if Applicant can make it clear that the scope of the instant claims excludes the addition of the interferon required by Poston *et al.*, it is believed that the present claims will be held patentable over the cited art.

To achieve this goal of excluding interferon, the present amendment changes the transitional phrase "comprising" to read "consisting essentially of" in the independent claims. It has been a long-standing concept that a claim to a composition "consisting essentially of" specified elements sufficiently distinguishes the composition over art compositions that require

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at least one additional ingredient (*In re Garnero*, 412 F.2d 276, 162 U.S.P.Q. 221, 223 (C.C.P.A. 1969)). In current practice, the guidelines of M.P.E.P. § 2111.03 qualify the distinction of the transitional phrases indicating that the U.S. Patent and Trademark Office will construe "consisting essentially of" as equivalent to "comprising" for purposes of applying prior art pursuant to 35 U.S.C. §§ 102 and 103, unless there is a clear indication in the specification or claims of what the basic and novel characteristics actually are. Looking closely at what the present specification teaches to one of ordinary skill in the art, it is found that the specification does exclude interferon from the vaccine composition used in the method of the invention.

The Examiner's attention is respectfully drawn to page 35, lines 13-20 of the specification where it is explained that prior to the experiments demonstrating the invention, it was postulated that presence of maternal antibodies would adversely affect the effectiveness of the vaccine. Example 4 nonetheless and surprisingly established that the *in ovo* administration of the TRT vaccine was efficacious in reducing clinical TRT disease in chickens that were MA+.

Equally surprising, all of the working examples in the specification demonstrate that the novel *in ovo* administration of the live, attenuated strain of turkey rhinotracheitis virus is safe and efficacious despite the teachings of Poston *et al.* that interferon is required to achieve safety and efficacy levels. It is stressed that nowhere in the instant specification is the inclusion of interferon recommended, promoted, let alone even discussed. It is clear from an overall reading of the specification and the claims that interferon is not even considered for use with the present invention. Any person skilled in the art would quickly understand that the invention is not about the co-administration of interferon in any manner whatsoever. In no uncertain terms, interferon is not embraced by the vaccine or method of the claimed invention. The specification and the claims, therefore, give a clear indication that the basic and novel characteristics of the present invention actually exclude interferon.

Since the interferon of Poston *et al.* is used for the express purposes of safening the live pathogenic vaccines and overcoming the inactivating effects of maternal antibodies (page 2, lines 7-21), Example 4 of the instant specification provides significant proof that Applicant's invention excludes the need for interferon and demonstrates surprising results over the art. Consequently, the transitional phrase "consisting essentially of" is available to define the claimed invention over Poston *et al.*

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Turning to the specific rejections at hand, the Examiner rejects Claims 1, 3-15 and 17-21, plus maintains the previous rejection of Claims 1, 3-9, 15, 17 and 18, under 35 U.S.C. § 102 (b) as allegedly being anticipated by Poston *et al.* (WO 99/53950) for reasons set forth on pages 3-5 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

To sustain the rejection, there must be an identity of invention between Applicant's invention and the vaccine of Poston *et al.* in which the single reference describes the claimed vaccines and methods. Since Poston *et al.* teach that interferon is critical to the effective and safe *in ovo* administration of live virus vaccines, the reference mandates that the interferon be present in each and every instance. The Abstract, the Detailed Description of the Invention, the Examples and the claims include interferon in conjunction with the live, pathogenic viruses. Plus, there is no disclosure of an *in ovo* vaccine having a live, attenuated TRT virus as the sole active ingredient. In sum, the reference is totally lacking an anticipating description of the claimed-designated *in ovo* methods and vaccines containing the TRT virus in the absence of interferon or the ND virus.

Moreover, the present claims have been amended to recite "consisting essentially of" that effectively acts to exclude the interferon of Poston *et al.*, further distinguishing Applicant's invention from the art. No identity of invention is seen to support the rejection based on anticipation.

In view of the foregoing remarks, the amendment and the total lack of identity of invention, it is respectfully requested that the rejection of Claims 1, 3-15 and 17-21 under 35 U.S.C. § 102 (b) be withdrawn.

The Examiner maintains the rejection of Claim 16 under 35 U.S.C. § 102 (b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Poston *et al.* for reasons set forth on page 5 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

For the same reasons as applied to the above anticipation rejection of Claims 1, 3-15 and 17-21, Poston *et al.* do not anticipate Claim 16 that is drawn to the method of administering a combination of viral vaccines. Interferon, which is described as an essential component of the method and pharmaceutical composition of the cited reference, is noticeably missing from Applicant's claims. The present amendment expressly excludes the critical component of interferon from the scope of the claimed invention. There is no identity of invention.

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Furthermore, the reference stresses that the administration of *in ovo* viral vaccines will be ineffective and unsafe in the absence of interferon, *i.e.*, Poston *et al.* explicitly suggest that interferon cannot be eliminated without deleterious effects. M.P.E.P. § 2144.04 indicates that the omission of an element with retention of the element's function is an indicia of unobviousness. By excluding the interferon of Poston *et al.* in the use of the transitional phrase "consisting essentially of" while retaining efficacy and safety properties, the combination method of Claim 16 is not rendered obvious by the teachings of the cited art.

In view of the foregoing remarks and the present amendment, it is clear to see that Poston *et al.* do not anticipate the claimed invention or render the claimed invention obvious. Consequently, Applicant respectfully asks that the rejection of Claim 16 under 35 U.S.C. § 102 (b) and 35 U.S.C. § 103(a) be withdrawn.

The Examiner maintains the rejection of Claims 2 and 22 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Poston *et al.* as applied to Claims 1, 3-9, 15, 17 and 18, above, and further in view of Ricks *et al.* for reasons set forth on pages 6 and 7 of the Office action. Applicant respectfully traverses the rejection for the following reasons.

As previously noted, the omission of an element with retention of the element's function is an indicator of unobviousness. Neither Poston *et al.* nor Ricks *et al.* imply that an *in ovo* method of administration can be safely and effectively employed with a broad range of pathogenic viruses in the absence of interferon. There is no suggestion or expectation that the crucial ingredient of interferon can be omitted from the vaccine of Poston *et al.* without significant loss of safety and efficacy when vaccinating a fragile, fertile egg with a highly pathogenic virus. It is therefore quite unexpected that the claimed method is safe and effective without the co-administration of interferon. Based on the combined teachings of Poston *et al.* and Ricks *et al.*, the practitioner would not be able to predict these results from the *in ovo* administration of TRTV of the present claims. The unexpected results overcome the art.

Further, by use of the transitional phrase "consisting essentially of," the present amendment excludes the interferon required by Poston *et al.* from the scope of the instant claims. Without a doubt, the claimed invention is clearly patentable over the combined art.

In view of the foregoing remarks and the present amendment, Applicant respectfully asks that the rejection of Claims 2 and 22 under 35 U.S.C. § 103(a) be withdrawn.

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Accordingly, this application is now in condition for an allowance and such favorable treatment is respectfully urged.

Respectfully submitted,
WYETH

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APPENDIX

AMENDMENTS TO THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently amended): A method for protecting an avian host from turkey rhinotracheitis (TRT), turkey rhinotracheitis-related (TRT-related) respiratory distress or Swollen Head Syndrome-related (SHS-related) respiratory distress ~~comprising~~ consisting essentially of administering a vaccine *in ovo* to a fertile egg containing an embryo of the avian host, said vaccine ~~comprising consisting essentially of~~ an immunogenically-effective amount of a live, attenuated strain of turkey rhinotracheitis virus in the approximate range of from about $10^{3.2}$ $TCID_{50}$ per egg to about $10^{5.5}$ $TCID_{50}$ per egg, wherein said vaccine is administered on or before day 24 of incubation.

Claim 2 (Original): The method of Claim 1, wherein said immunogenically-effective amount is administered in a suitable vehicle of approximately 0.05 to 0.1 ml per egg.

Claim 3 (Original): The method of Claim 2, wherein the immunogenically-effective amount is about $10^{3.2}$ $TCID_{50}$ per egg.

Claim 4 (Original): The method of Claim 2, wherein the immunogenically-effective amount is about $10^{4.2}$ $TCID_{50}$ per egg.

Claim 5 (Original): The method of Claim 1, wherein said avian host is a turkey or chicken embryo.

Claim 6 (Original): The method of Claim 5, wherein said administration occurs on approximately day 18 of incubation (chicken) or approximately day 24 of incubation (turkey).

Claim 7 (Original): The method of Claim 3, wherein the avian host is either a turkey or a chicken embryo.

Claim 8 (Original): The method of Claim 7, wherein the avian host is a turkey embryo.

Claim 9 (Original): The method of Claim 7, wherein the avian host is a chicken embryo.

Claim 10 (Currently amended): A process for protecting turkeys or chickens against infection from exposure to virulent strains of turkey rhinotracheitis virus, ~~comprising~~ consisting essentially of administering *in ovo* to fertile eggs a vaccine ~~comprising~~ consisting essentially of, on a per egg basis, an immunogenically-effective amount of a live, avirulent strain of turkey rhinotracheitis virus, wherein said administration results in a decrease in the percentage of eggs that hatch of less than about 2%.

Claim 11 (Original): The process of Claim 10, wherein the immunogenically-effective amount is in the approximate range of from about $10^{3.2}$ $TCID_{50}$ per egg to about $10^{4.2}$ $TCID_{50}$ per egg.

Claim 12 (Currently amended): An *in ovo* vaccine for protecting turkeys or chickens against infection from exposure to virulent turkey rhinotracheitis virus, ~~comprising~~ consisting essentially of a buffered solution containing, on a per egg basis, a live, attenuated strain of turkey rhinotracheitis virus in an immunogenically-effective amount of from about about $10^{3.2}$ $TCID_{50}$ to about $10^{5.5}$ $TCID_{50}$.

Claim 13 (Previously presented): The vaccine of Claim 12, wherein the immunogenically-effective amount is efficacious against subsequent post-hatch exposure of the turkey or the chicken to virulent turkey rhinotracheitis virus; and produces substantially no decrease in the percentage of *in ovo* vaccinated turkey or chicken eggs that hatch upon the expiration of the incubation period.

Claim 14 (Original): The vaccine of Claim 13, wherein the immunogenically-effective amount is about $10^{4.2}$ $TCID_{50}$.

Claim 15 (Currently amended): A method for inoculating poultry against turkey rhinotracheitis (TRT) disease which ~~comprises~~ consists essentially of administering an immunologically effective amount of a live, attenuated strain of turkey rhinotracheitis (TRT) virus in a pharmaceutically acceptable carrier *in ovo* within the range of at least about $10^{3.2}$ $TCID_{50}$ per egg to about $10^{5.5}$ $TCID_{50}$ per egg.

Claim 16 (Currently amended): The method of Claim 15, which further ~~comprises~~ consists essentially of administering together with said turkey rhinotracheitis virus (TRTV) at least one other vaccine selected from the group consisting of Newcastle Disease vaccine and infectious bursal disease vaccine.

Claim 17 (Currently amended): The method of Claim 16, further ~~comprising~~ consisting essentially of administering at least one vaccine selected from the group consisting of infectious bronchitis vaccine and Marek's disease vaccine, wherein said vaccine is administered post-*in ovo*.

Claim 18 (Previously presented): The method of Claim 17, wherein said vaccine being administered post-*in ovo* is administered at approximately day 1 of age.

Claim 19 (Original): The method of Claim 15, wherein said method results in substantially no decrease in the number of eggs that hatch.

Claim 20 (Original): The method of Claim 15, wherein said method produces a decrease in the percentage of eggs that hatch of less than about 5%.

Claim 21 (Previously presented): The method of Claim 20, wherein said method produces a decrease in the percentage of eggs that hatch of less than about 1%.

Claim 22 (Currently amended): A method of providing elevated titers to turkey rhinotracheitis virus (TRTV), which ~~comprises~~ consists essentially of formulating an *in ovo* vaccine of attenuated turkey rhinotracheitis virus (TRTV) antigen, and administering said vaccine so as to provide a $TCID_{50}$ in the range of about $10^{3.2}$ to about $10^{5.5}$ per egg within a vehicle of approximately 0.05 to 0.1 mL per egg.